

Meeting Minutes

**The Ethylene Oxide Sterilization Association, Inc.
Executive Committee**

Conference Call

**July 31, 2018
9:00 a.m. (EDT)**

On July 31, 2018, the Executive Committee of the Ethylene Oxide Sterilization Association, Inc. (EOSA) convened a meeting via conference call. In attendance were:

Katie Biri, Midwest Sterilization Corporation
Bob Bogart, ARC Specialty Products
Jonathan Bull, Johnson & Johnson
Joanne Cashin, ARC Specialty Products (part-time)
Venice Eldred, Medline Industries, Inc.
Marga Foster, Medline Industries, Inc.
Kathy Hoffman, Sterigenics
Clark Houghtling, Cosmed Group, Inc.
Rob Howard, Cosmed Group, Inc.
Chris Klosen, ARC Specialty Products
Dave Ludwig, ARC Specialty Products
Brian McEvoy, Steris
Christine Render, Cosmed Group, Inc.
Fenil Sutaria, Medline Industries, Inc.
Jake Vandevort, B&C® Consortia Management, L.L.C. (BCCM)

1. Administrative Issues

- 1.1. **Welcome** -- Bull welcomed everyone and called the meeting to order at approximately 9:05 a.m. (EDT).
- 1.2. **Antitrust Reminder** -- Vandevort provided the antitrust reminder.
- 1.3. **Approval of Minutes** -- Members approved the June 26, 2018, minutes as distributed. Vandevort will prepare the minutes in final, but will not redistribute them to the group.

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- 1.4. **Budget Review** -- Members reviewed the June 30, 2018, budget and year-end projections. Discussion of the **2019** budget proposal was deferred to the **August 28, 2018**, conference call.
 - 1.5. **Next Conference Call** -- Members were reminded that the next conference call is scheduled for **August 28, 2018, at 9:00 a.m. (EDT)**.
2. **Risk Assessment for Ethylene Oxide (EO)** -- Ludwig and Hoffman reported on efforts to develop an alternative risk assessment to the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) unit inhalation risk value for EO. The National Institute for Occupational Safety and Health (NIOSH) study relied upon by EPA in its IRIS assessment suggests that use of EO in earlier decades was more controlled and resulted in lower exposures than actually occurred. This leads to the extreme slope in the exposure models at low concentrations. The goal of the alternative risk assessment is to revisit the effects of lower exposures in the 1950s and 1960s to counter the published IRIS value.

Jane Teta and Abby Li (Exponent) will be leading this activity. Exponent will work to conduct interviews with those in the industry that may have anecdotal information on exposures and practices in past decades. The proposal is for EOSA to provide \$35,000 in support, with the American Chemistry Council's (ACC) EO panel also contributing support to the effort. Based on discussions between ACC and the Texas Commission on Environmental Quality (TCEQ), TCEQ has indicated its receptiveness to considering an alternative to the IRIS value.

The Executive Committee agreed, in principle, to support the work as a valuable opportunity to counter the IRIS assessment. Cashin will request a formal proposal from Li and provide it to Vandevort for distribution. The Executive Committee will reconvene on **August 8, 2018, at 9:00 a.m. (EDT)** to discuss the proposal and next steps.
3. **International Matters** -- Discussion of residual issues in Europe, revisions to International Standards Organization (ISO) 10993-7:2008, the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, and the EU Biocides review was deferred to the **August 28, 2018**, conference call.
4. **Revisions to Bylaws** -- Approval of proposed revisions to the bylaws was deferred to the **August 28, 2018**, conference call.

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5. **Benefits Messaging** -- Review and discussion of benefits messaging was deferred to the **August 28, 2018**, conference call.
6. **General Membership Meeting** -- Discussion of matters regarding the next general membership meeting was deferred to the **August 28, 2018**, conference call.
7. **Technical Conference** -- No updates were reported. Tim Carlson will provide updates during the next conference call.
8. **Other** -- No other business matters were discussed.
9. **Summary of Action Items** -- Action items are identified below:
 - 9.1. Vandevort will prepare the June 26, 2018, minutes in final, but will not redistribute them to the group.
 - 9.2. Discussion of the **2019** budget proposal was deferred to the **August 28, 2018**, conference call.
 - 9.3. Cashin will request a formal proposal from Li and provide it to Vandevort for distribution.
 - 9.4. The Executive Committee will reconvene on **August 8, 2018, at 9:00 a.m. (EDT)** to discuss the proposal and next steps.
 - 9.5. Discussion of residual issues in Europe, revisions to ISO 10993-7:2008, REACH, and the EU Biocides review was deferred to the **August 28, 2018**, conference call.
 - 9.6. Approval of proposed revisions to the bylaws was deferred to the **August 28, 2018**, conference call.
 - 9.7. Review and discussion of benefits messaging was deferred to the **August 28, 2018**, conference call.
 - 9.8. Discussion of matters regarding the next general membership meeting was deferred to the **August 28, 2018**, conference call.

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- 9.9. Carlson will provide updates during the next conference call.
10. **Adjourn** -- There being no further business, the call adjourned at approximately 10:05 a.m. (EDT).

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January 30, 2018, Action Items

- Vandevort will circulate a final year-end budget once the financials are available.
- Vandevort will work with Roberts to determine whether BCCM has worked with others to perform similar audits in the past. This matter will be discussed during the next conference call.
- Executive Committee members agreed to revisit the EOSA bylaws on existing membership categories in **May**.
- Vandevort will circulate TCEQ materials regarding EO and current activities.
- Vandevort will circulate an update on the ACGIH Under Study list once it is available.
- Vandevort will work with Gulledge to identify a potential alternate speaker for the general membership meeting.
- Vandevort will circulate the ongoing list of potential presentation topics.
- During the next conference call, Executive Committee members will work to identify presentation topics through the **March 2019** meeting.

February 27, 2018, Action Items

- Vandevort will prepare, but not distribute, the final January 30, 2018, minutes.
- Vandevort will circulate the January 31, 2018, budget report by **March 9, 2018**.
- By **March 2, 2018**, Vandevort will prepare for review by Houghtling a statement to the Executive Committee confirming that independent audits of all EOSA financial matters are prepared by CLA.
- By **March 9, 2018**, Vandevort will circulate to the Executive Committee for review and approval proposed edits to the existing bylaws.
- Executive Committee members will review the proposed changes to the bylaws and provide approval and/or further edits by **March 16, 2018**.
- Vandevort will update the Outlook invitations to reflect the Executive Committee conference call schedule change and add international members to the invitation list.
- By **March 6, 2018**, Vandevort will prepare for review by the Executive Committee a draft letter reiterating the concerns presented to AAMI in EOSA's October 27, 2017, letter. Vandevort will recirculate the October 2017 letter and AAMI response with the draft letter.
- Vandevort will continue to monitor the evaluation of EO under the Australia IMAP and provide updates as information is made available.
- Vandevort will circulate the EU press release and directive.

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- ~~McEvoy will work to identify the current status of the Malaysia ban and provide additional information to Vandevort for distribution.~~ Hoffman will request updates on this matter from her colleagues.
- ~~Vandevort will circulate a general e-mail on EPA's request for assistance to the full membership to be followed by individual communications to those members for which EPA has selected facilities.~~
- ~~Vandevort will continue to monitor the status of EO under the SCP Regulation and provide updates on new developments.~~
- ~~Vandevort will circulate additional information on the ODEQ ABC for EO as it becomes available.~~
- ~~Vandevort will continue to monitor development of the DSD by TCEQ and report on new developments. For reference, Vandevort will circulate the 2016 DSD for ethylene glycol.~~
- ~~Vandevort will circulate a spreadsheet identifying state regulatory activities by **March 5, 2018.**~~
- ~~Maamari will present on emissions and abatement technologies and challenges in efforts to reduce emissions during the next general membership meeting. Hoffman will introduce Maamari and the general topic during the meeting.~~
- ~~Maamari will provide a copy of his presentation to Vandevort for review prior to the general membership meeting.~~
- ~~Vandevort will work with Gullede to determine his availability to present at the fall general membership meeting.~~
- The Executive Committee will discuss and identify topics for the **March 2019** membership meeting during the next conference call.

June 26, 2018, Action Items

- ~~Vandevort will prepare the February 27, 2018, minutes in final, but will not redistribute them to the group.~~
- ~~Vandevort will work with Houghtling to prepare a **2019** budget proposal by **July 20, 2018.**~~
- ~~Executive Committee members will review and approve the budget proposal during the next conference call.~~
- Moving forward, Vandevort will account for time spent on all aspects of the general membership meetings on the separate line item of the budget.
- Vandevort will recirculate the draft edits to the bylaws and summarize the options discussed by **July 6, 2018**, and work with the Executive Committee to schedule a conference call to review the potential edits and available options.

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- ~~Vandevort will request that a conference call be scheduled between AAMI and EOSA to discuss residual matters prior to the September 2018 International Organization for Standardization (ISO) meeting.~~
- ~~Vandevort will request that AAMI identify who will be present on the call so that EOSA may have the appropriate representation available.~~
- Vandevort will continue to monitor matters regarding the REACH directive and work with McEvoy to provide additional information as it becomes available.
- ~~Vandevort will circulate to the Executive Committee a proposed response to EPA regarding its request to validate emissions data.~~
- EOSA will initially develop a one page benefits statement for EO sterilization.

- ~~Vandevort will contact Gulledge to discuss advocacy matters and benefits of EO sterilization.~~
- ~~Vandevort will circulate to the Executive Committee by July 6, 2018, an updated list of benefits talking points to begin development of the one page document.~~

July 31, 2018, Action Items

- ~~Vandevort will prepare the June 26, 2018, minutes in final, but will not redistribute them to the group.~~
- Discussion of the **2019** budget proposal was deferred to the **August 28, 2018**, conference call.
- ~~Cashin will request a formal proposal from Li and provide it to Vandevort for distribution.~~
- ~~The Executive Committee will reconvene on August 8, 2018, at 9:00 a.m. (EDT) to discuss the proposal and next steps.~~
- Discussion of residual issues in Europe, ISO 10993-7:2008, REACH regulation, and the EU Biocides review was deferred to the **August 28, 2018**, conference call.
- Approval of proposed revisions to the bylaws was deferred to the **August 28, 2018**, conference call.
- Review and discussion of benefits messaging was deferred to the **August 28, 2018**, conference call.
- Discussion of matters regarding the next general membership meeting was deferred to the **August 28, 2018**, conference call.
- Carlson will provide updates during the next conference call.